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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,967	12/26/2001	Shigeru Kamei	087147-0443B	2213

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,967	KAMEI ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A restriction is imposed, as set forth below. First, however, the following subgenera are defined:

G1: formation of an O/W emulsion is required as part of the process

G2: formation of an O/W emulsion is not required as part of the process

✧

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-18, drawn to a sustained-release preparation.

II. Claims 19-22 and 24, drawn to a method of preparing a sustained-release preparation, limited to G2.

III. Claims 23 and 25, drawn to a method of preparing a sustained-release preparation, limited to G1.

Groups {II, III} and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). However, in the event that Group I is elected, and claims therein found allowable, claims drawn to a method of preparing the sustained-release preparation (that has been determined to be novel and

otherwise allowable) will be rejoined for further examination.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group I is elected, election of the following is required:

(a) a specific physiologically active peptide that is present in the elected composition;

(b) fully described "biodegradable polymer". If the polymer is homogeneous in composition (i.e., not a mixture of polymers or copolymers), what is the approximate molecular weight? In the event that the "biodegradable polymer" is a mixture of polymers (as in claims 6 and 20), what is the molecular weight of each of the separate polymers? In the event that the "biodegradable polymer" is that which is recited in claim 6 (or claim 20), what alkyl group corresponds to "R"...? In the event that the "biodegradable polymer" is chiral, what is the approximate D/L ratio of the monomers from which it is derived?

(c) a statement as to whether the claimed composition is in the form of microcapsules, or not in the form of microcapsules;

(d) regardless of whether the elected composition (i.e., the final product) is in the form of microcapsules or not in the form of microcapsules, is the final form that of a solid or a liquid (page 30, line 5+; page 31, line 18+)? If a solid, is the final form that of capsules or granules or powders, and if a liquid is it a syrup, emulsion or suspension?

(e) a statement as to what other compounds or materials (if any) are present in the

elected composition, apart from the peptide and polymer identified above;

. . . .

In the event that Group II is elected, election of the following is required:

(a) a specific physiologically active peptide that is present

(b) a fully described "biodegradable polymer" that is present in the composition. If the polymer is homogeneous in composition (i.e., not a mixture of polymers or copolymers), what is the approximate molecular weight? In the event that the "biodegradable polymer" is a mixture of polymers (as in claims 6 and 20), what is the molecular weight of each of the separate polymers? In the event that the "biodegradable polymer" is that which is recited in claim 6 (or claim 20), what alkyl group corresponds to "R"...? In the event that the "biodegradable polymer" is chiral, what is the approximate D/L ratio of the monomers from which it is derived?

(c) a statement as to whether the claimed composition is in the form of microcapsules, or not in the form of microcapsules

(d) regardless of whether the final product is in the form of microcapsules or not in the form of microcapsules, is the final form that of a solid or a liquid (page 30, line 5+; page 31, line 18+)? If a solid, is the final form that of capsules or granules or powders, and if a liquid is it a syrup, emulsion or suspension?

(e) a statement as to what other compounds or materials (if any) are present in the elected composition (the final product), apart from the peptide and polymer identified above;

(f) a statement as to whether an emulsifier is used in the process (see, page 27, line 26+), and if so, the identity of the emulsifier.

(g) a specific water-insoluble solvent (or mixture of solvents) in which the peptide and the polymer are to be dissolved;

(h) in the event that the final product is in the form of microcapsules, is the "drying in water" technique used, or the "phase separation" technique (page 26, line 30+)...?

(i) is a "coacervation agent" required (page 28, line 35), and if so, what is the

coacervation agent?

(j) is an "aggregation inhibitor" required (page 29, line 14+) in the process, and if so, which one is used?

. . . .

In the event that Group III is elected, election of the following is required:

(a) a specific physiologically active peptide that is present;

(b) a fully described "biodegradable polymer" that is present in the composition. If the polymer is homogeneous in composition (i.e., not a mixture of polymers or copolymers), what is the approximate molecular weight? In the event that the "biodegradable polymer" is a mixture of polymers (as in claims 6 and 20), what is the molecular weight of each of the separate polymers? In the event that the "biodegradable polymer" is that which is recited in claim 6 (or claim 20), what alkyl group corresponds to "R"...? In the event that the "biodegradable polymer" is chiral, what is the approximate D/L ratio of the monomers from which it is derived?

(c) a statement as to whether the claimed composition is in the form of microcapsules, or not in the form of microcapsules;

(d) regardless of whether the final product is in the form of microcapsules or not in the form of microcapsules, is the final form that of a solid or a liquid (page 30, line 5+; page 31, line 18+)? If a solid, is the final form that of capsules or granules or powders, and if a liquid is it a syrup, emulsion or suspension?

(e) a statement as to what other compounds or materials (if any) are present in the elected composition (the final product), apart from the peptide and polymer identified above;

(f) a statement as to whether an emulsifier is used in the process (see, page 27, line 26+), and if so, the identity of the emulsifier;

(g) a specific water-insoluble solvent (or mixture of solvents) in which the peptide and the polymer are to be dissolved;

(h) a specific oil that is to be used to form the O/W emulsion ;

(i) in the event that the final product is in the form of microcapsules, is the "drying in water" technique used, or the "phase separation" technique (page 26, lin 30+)...?

(j) is a "coacervation agent" required (page 28, line 35), and if so, what is the coacervation agent?

(k) is an "aggregation inhibitor" required (page 29, line 14+) in the process, and if so, which one is used?

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during

prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1600